General

Guideline Title

Ocular prophylaxis for gonococcal ophthalmia neonatorum: U.S. Preventive Services Task Force reaffirmation recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force (USPSTF). Ocular prophylaxis for gonococcal ophthalmia neonatorum: U.S. Preventive Services Task Force reaffirmation recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2011 Jul. 6 p. [7 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force (USPSTF). Screening for gonorrhea: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2005. 11 p. [13 references]

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum. This is a grade A recommendation.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to all newborns.

Preventive Medication

Prophylactic regimens using 1.0% tetracycline or 0.5% erythromycin ophthalmic ointment are considered equally effective in the prevention of gonococcal ophthalmia neonatorum; however, the only drug approved by the U.S. Food and Drug Administration for this indication is 0.5% erythromycin ophthalmic ointment. Tetracycline ophthalmic ointment and silver nitrate are no longer available in the United States. A 2.5% solution

of povidone-iodine may be useful in preventing ophthalmia neonatorum, but it has not been approved for use in the United States at this time.

Optimal Timing

Prophylaxis should be provided within 24 hours after birth.

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies

Level of Certainty	Description
	• Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Gonococcal ophthalmia neonatorum

Guideline Category

Prevention

Clinical Specialty

Family Practice

Infectious Diseases

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To summarize the U.S. Preventive Services Task Force (USPSTF) recommendations on ocular prophylaxis for gonococcal ophthalmia neonatorum

Target Population

All newborns

Interventions and Practices Considered

Prophylactic ocular topical medication within 24 hours of birth for all newborns

Note: Prophylactic regimens using 1.0% tetracycline or 0.5% erythromycin ophthalmic ointment are considered equally effective in the prevention of gonococcal ophthalmia neonatorum; however, the only drug approved by the U.S. Food and Drug Administration for this indication is 0.5% erythromycin ophthalmic ointment. Tetracycline ophthalmic ointment and silver nitrate are no longer available in the United States. A 2.5% solution of povidone-iodine may be useful in preventing ophthalmia neonatorum, but it has not been approved for use in the United States at this time.

Major Outcomes Considered

- Benefits and harms of prophylactic treatment
- Incidence of gonococcal ophthalmia neonatorum
- Morbidity (i.e., scarring, ocular perforation, and blindness)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A targeted review of the literature was prepared by the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Literature Search Process for the Reaffirmation Evidence Update

AHRQ staff performed a targeted literature search for the benefits and harms of prophylaxis of gonococcal ophthalmia neonatorum. The literature search was limited to the period of January 1, 1995, to March 1, 2009.

The databases searched were PubMed and the Cochrane Library. A series of searches using combinations of medical subject headings (MeSH) terms and keywords were performed, and the results were limited to core journal articles. Results were supplemented with recommendations from subject matter experts and reference list reviews.

All articles were reviewed for predetermined inclusion/exclusion criteria by two team members at each stage of review (title, abstract, full article). A consensus process was used to resolve any reviews which resulted in differences of opinion.

PubMed search strategy:

Limited to:

- English
- Human
- Infant
- Publication date from 01/01/1995 to 03/01/2009

For benefits:

- MeSH terms: "conjunctivitis," "screening," "chlamydia infections," "gonorrhea"
- Limited to: randomized controlled trials, meta-analysis, systematic reviews

For harms:

- MeSH terms: "drug toxicity," "drug hypersensitivity," "silver nitrate," "tetracycline," "erythromycin," "povidone-iodine"
- Other terms: "harms," "adverse effects"

For a complete list of literature search exclusion criteria, refer to Appendix 2 of the Evidence Update (see the "Availability of Companion Documents" field).

Number of Source Documents

The application of inclusion/exclusion criteria resulted in 118 articles. After a sequential review of the titles, abstracts, and full text, one article remained.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A, B, C, D,* and *I (Insufficient)* represent the letter grades of recommendation or of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as

"high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

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C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence

Level of Certainty	Description
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the Task Force Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comments. A draft of this reaffirmation was posted for public comment on the USPSTF Web site from August 16, 2010 to September 13, 2010. Nineteen comments were received from individuals or organizations. All comments were reviewed in the creation of this final document.

Comparison with Guidelines from Other Groups. Recommendations regarding ocular prophylaxis for gonococcal ophthalmia neonatorum were considered from the following groups: The American Academy of Pediatrics, Centers for Disease Control and Prevention, World Health Organization, Canadian Task Force on Preventive Health Care, American Academy of Family Physicians, and Canadian Paediatric Society.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Reducing risk for gonococcal ophthalmia neonatorum in newborn infants

Benefits of Risk Assessment and Preventive Medication

There is convincing evidence that blindness due to gonococcal ophthalmia neonatorum has become rare in the United States since the implementation of universal prophylaxis of newborns.

Potential Harms

There is convincing evidence that universal prophylaxis of newborns is not associated with serious harms.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.
- Recommendations are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision making to the specific patient or situation.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF Task Force will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and

incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Mobile Device Resources

Pocket Guide/Reference Cards

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

U.S. Preventive Services Task Force (USPSTF). Ocular prophylaxis for gonococcal ophthalmia neonatorum: U.S. Preventive Services Task Force reaffirmation recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2011 Jul. 6 p. [7 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2011 Jul)

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

Source(s) of Funding

United States Government

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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**Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to http://www.uspreventiveservicestaskforce.org/Page/Name/our-members*.

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force (USPSTF). Screening for gonorrhea: recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2005. 11 p. [13 references]

Guideline Availability

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Availability of Companion Documents

The following are available:

Evidence Review:

- Mabry-Hernandez I, Oliverio-Hoffman R. Ocular prophylaxis for gonococcal ophthalmia neonatorum: evidence update for the U.S. Preventive Services Task Force Reaffirmation Recommendation Statement. AHRQ Publication No. 10-05146. Rockville, MD: Agency for Healthcare Research and Quality; 2010. 9 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med 2007;147:871-875.

Electronic copies: Available from the USPSTF Web site .

The following are also available:

- Ocular prophylaxis for gonococcal ophthalmia neonatorum: clinical summary of U.S. Preventive Services Task Force reaffirmation recommendation. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2011. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site .
- The guide to clinical preventive services, 2010-2011. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2010. 292 p. Electronic copies: Available from the AHRQ Web site . See the related QualityTool summary on the Health Care Innovations Exchange Web site .

The Electronic Preventive Services Selector (ePSS) , available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on May 24, 2005. The information was verified by the guideline developer on May 26, 2005. This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs. This NGC summary was updated by ECRI Institute on October 12, 2011. The information was verified by the guideline developer on October 24, 2011.

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